

desired state was compromised by the difficulty of recruiting doctors and patients and keeping those recruited engaged. In the end, the study doesn't inform us about whether the community's mental health was improved. Sadly, the multiple barriers to doing health services research and implementing innovative health services are why so few investigators try to do effectiveness studies. And even if they succeed, healthcare managers, planners, and politicians will want to know more than "Does it work?": they will want to know "Is it worth it?"—in comparison with use of the resources for other needs.

But don't despair. We're simply going through an evolutionary phase in testing interventions. Since the end of the second world war we've learned to walk, with randomised trials that assess efficacy. Trials such as the one by Llewellyn-Jones et al show that we're just now learning to run—with community trials that tackle difficult challenges in research design and implementation that can undermine the feasibility of a study or prejudice the interpretation of its findings. Issues of economic analysis also are being resolved, so that questions of efficiency can be better addressed. This progress will seem slow to researchers caught up in it and to all of us waiting for the answers, but in the history of the world we're heading for success at a blistering pace. Our progress is fuelled by efficacy studies and

by researchers and governments intent on reaping the benefits they promise.

We need more effectiveness studies to sort the fool's gold from the true gold and efficiency studies to tell us if the price of extraction is a bargain. Fortunately, many governments around the world are aware of the need for more and better research into health services and are providing funds for training and research development. One hopes that they will not lose heart or patience: we're going in the right direction, but trial and error are needed, along with investment in methodological research to get effectiveness and efficiency studies right.

Brian Haynes *professor of clinical epidemiology and medicine*

McMaster University Health Sciences Center, Hamilton, Ontario
L8N 3Z5, Canada

- 1 Cochrane AL. *Effectiveness and efficiency: random reflection on health services*. London: Nuffield Provincial Hospitals Trust, 1972.
- 2 Sackett DL, Gent M. Controversies in counting and attributing events in clinical trials. *N Engl J Med* 1979;301:1410-2.
- 3 Bennett K, Tugwell P, Sackett D, Haynes B. Relative risks, benefits, and costs of intervention. In: Warren KS, Mahmoud AAF, eds. *Tropical and geographic medicine*. 2nd ed. New York: McGraw-Hill, 1990: 205-28.
- 4 Llewellyn-Jones RH, Baikie KA, Smithers H, Cohen J, Snowdon J, Tennant CC. Multifaceted shared care intervention for late life depression in residential care: randomised controlled trial. *BMJ* 1999; 319:676-82.

Accepting commercial sponsorship

Disclosure helps—but is not a panacea

Earlier this summer the Royal College of Paediatrics and Child Health published a report describing its policies towards accepting industry sponsorship.¹ The ethics advisory committee that wrote the report was formed in response to controversy surrounding the college's acceptance and lack of disclosure of sponsorship from Nestlé, a manufacturer of breast milk substitutes. The acceptance of the money from Nestlé was hotly debated among college members because breast milk substitutes are associated with infant deaths in developing countries and do not provide the same health advantages as breast feeding. The college voted 73% in favour of continuing to accept sponsorship from baby food manufacturers but recommended that it should define criteria for ethical sponsorship. An examination of the college's resulting report and its recommendations may offer some help to other organisations struggling with the same issue.

Overwhelming evidence exists that single source sponsorship is associated with outcomes favourable to the sponsor's product.²⁻⁴ Although most documentation of industry influence on research concerns the pharmaceutical and tobacco industries, other types of corporate sponsors are also known to influence research reports.^{5,6} One reason why published research favours the sponsor's product is because sponsors sometimes suppress publication of unfavourable findings.⁷ Single source sponsorship can also influence decisions, such as prescribing decisions, that are more directly related to patient care.⁸ In addition to

the empirical data on the influences of industry sponsorship, doctors' acceptance of money and gifts from corporate sponsors creates a relationship with the sponsor. Doctors may then feel favourable towards, or even obligated to, that sponsor.^{9,10}

The Royal College of Paediatrics and Child Health's report states that the college's guiding principle is that all its activities should be in the best interests of children worldwide. However, it is also concerned about the public perception of accepting commercial sponsorship—and the desire to produce favourable public perceptions may indeed be the driving force behind these recommendations. The recommendations for reducing both the real and the perceived influences of industry funding include designating sources of sponsorship as acceptable or not and, if acceptable, establishing restrictions on sponsorship.

The report attempts to differentiate sponsors that are acceptable from those that are not, yet these distinctions are slippery. Sponsorship from or investment in any company which produces tobacco, manufactures arms, or exploits children is unacceptable, while sponsorship from companies which market pharmaceutical products, medical equipment, or mineral water is deemed acceptable. The college has based this distinction on how the products are used or marketed and not on the products themselves. However, assessing the ethical practices of companies in an international market with frequent mergers and acquisitions is a formidable task. Companies falling into a middle category include those manufacturing

alcohol, sweetened drinks, and breast milk substitutes, and sponsorship by such companies is likely to remain controversial. The college might therefore be better off focusing on its second strategy of establishing restrictions on sponsorship, regardless of its source.

The college recommends a series of restrictions that apply to any acceptable sponsorship. Firstly, all sponsorship must be fully and transparently recorded in the college accounts and should be disclosed on the college website, by the units and departments accepting money, and in educational materials. Full disclosure of industry support forces individual members of the college to ask whether "they would be happy for it to be generally known that they are receiving sponsorship."¹ However, disclosure is not a panacea. Disclosure does not necessarily eliminate the influence of industry funding on research or doctors' behaviour. Moreover, patients and the public may distrust organisations or doctors who are funded by unpopular sources.¹¹ Lastly, disclosure may be difficult to enforce, as suggested in a recent study showing that 70% of articles from journals with disclosure policies made no mention of potential conflicts.¹² The report's recommendation that a committee should be established to monitor the information given about sponsorship by the members of the college is, however, a step towards ensuring that accurate disclosure occurs.

Secondly, sponsorship from companies producing breast milk substitutes or others in the middle category is not acceptable for general college activities but is acceptable for named activities such as travelling fellowships. Therefore, individuals can choose not to accept funds derived from baby food manufacturers. This "ethics shifting" (A Shulz, personal communication) is comparable to cost-shifting in economics—where the burden (in this case, the unethical decision) is transferred from the group to the individual. In effect the organisation avoids making a decision.

Thirdly, the college recommends that sponsorship for individuals should be modest, although a lower limit

for sponsorship that lacks influence has not been established.¹³ The cumulative amount of sponsorship, as well as each individual amount, should be taken into account.

Fourthly, the college recommends that sponsored investigators should retain control over the publication of results, regardless of their outcome. This important restriction could help to eliminate some of the influence of single sponsors over research outcomes.

If the college enforces its restrictions on sponsorship, and considers extending them to all corporate sponsors, it will set a strong example for other organisations that must deal with the reality of accepting increasing corporate sponsorship while maintaining ethical standards.

Lisa A Bero *associate professor*

Clinical Pharmacy and Health Policy, University of California, San Francisco, San Francisco, CA 94143-0936, USA
(bero@medicine.ucsf.edu)

- 1 Royal College of Paediatrics and Child Health. *Commercial sponsorship in the Royal College of Paediatrics and Child Health*. London: Royal College of Paediatrics and Child Health, 1999.
- 2 Davidson RA. Source of funding and outcome of clinical trials. *J Gen Intern Med* 1986;1:155-8.
- 3 Cho MK, Bero LA. The quality of drug studies published in symposium proceedings. *Ann Intern Med* 1996;124:485-9.
- 4 Rochon PA, Gurwitz JH, Cheung CM, Hayes JA, Chalmers TC. Evaluating the quality of articles published in journal supplements compared with the quality of those published in the parent journal. *JAMA* 1994;272:108-13.
- 5 Rabin R. Warnings unheeded: a history of child lead poisoning. *Am J Pub Health* 1989;79:1668-74.
- 6 Godlee F. The food industry fights for salt. *BMJ* 1996;312:1239-40.
- 7 Rennie D. Thyroid storm. *JAMA* 1997;277:1238-43.
- 8 McKinney WP, Schiedermayer DL, Lurie N, Simpson DE, Goodman JL, Rich EC. Attitudes of internal medicine faculty and residents toward professional interaction with pharmaceutical sales representatives. *JAMA* 1990;264:1693-7.
- 9 Chren M-M, Landefeld CS. Physicians' behavior and their interactions with drug companies. *JAMA* 1994;271:684-9.
- 10 Chren M, Landefeld CS. Does a doctor's interaction with a drug company influence on prescribing that doctor's behavior? Evidence of company-specific behavior. *Clin Res* 1992;40:302A.
- 11 Rothman K. The new McCarthyism in science. *JAMA* 1993;269:2782-4.
- 12 Blumenstyk G. Scientific journals rarely disclose authors' potential conflicts, study finds. *Chronicle of Higher Education* 1999; 28 Jan.
- 13 Chren M, Landefeld C, Murray T. Doctors, drug companies, and gifts. *JAMA* 1989;262:3448-51.

Legal safeguards for the audit process

Are essential for effective clinical governance

Clinicians are under siege from patients and politicians alleging limitations in professional self regulation. In Britain the General Medical Council's attempts to retrieve the situation are criticised by some as belated, or even unjust,¹ and the emergence of clinical governance in the NHS is regarded by some as an arbitrary system for imposing uniform standards and monitoring compliance. Are such misgivings reasonable? Clinical governance should promote high quality care by making individuals accountable for setting, maintaining, and monitoring standards, to produce a hitherto elusive culture of clinical excellence.² Systems of clinical risk management and audit should contribute to this process by facilitating greater self evaluation, open debate about clinical practice, and the routine investigation of adverse events. For clinicians to learn and improve, conclusions reached during these processes need to be

documented. Clinicians also need to feel safe with the process and that it will not be used against them.

In practice these worthy objectives are undermined by two legal concerns relating to confidentiality and to disclosure of documents before litigation. Firstly, problems relating to confidentiality arise when clinical audit becomes multidisciplinary, as prescribed for effective risk management.³ Although worthwhile audit may theoretically exist without identifying individuals, practical experience suggests that open meetings function best when the clinicians taking part can identify patients and recollect circumstances that influenced their decisions. Open and informed discussion must be documented to enhance educational value, allow reference to clinical records, and provide evidence of the clinical governance process.

Threats to this process posed by patients' rights of confidentiality may be more apparent than real, in that

BMJ 1999;319:654-5